REMARKS

1. Amendments to the Claims

Claims 1, 4, 6-11 and 13-27 were examined in the Office Action of June 8, 2010. The claims were amended with the response filed on November 5, 2010, which fully responded to the Office Action of June 8, 2010. An RCE was simultaneously filed, thus the claim amendments of November 5, 2010 have been entered. The claim amendments presented herein are based on the claim set filed on November 5, 2010.

Claims 4 and 19 are herein cancelled. Claims 1, 6, 7, 11, 13-17, 20, and 25-27 are herein amended.

Claim 1 is amended to incorporate claim 4. Support for this amendment can be found in the Specification at page 20, lines 19-20. Claim 1 is also amended without prejudice or disclaimer to recite "wherein the methylcellulose does not overall cover over the medicament, and a part of the medicament exists on the surface of the particle." Explicit support for this language can be found in the Specification, page 21, lines 7-9.

Claims 6 and 7 are amended to account for the cancellation of claim 4.

Claim 11 is amended to move the recitation of a "pharmaceutical preparation." Claims 13-17 are amended to recite a "pharmaceutical preparation" to be consistent with claim 11.

Claim 20 is amended without prejudice or disclaimer to delete the "water containing solvent."

Claims 25-27 are amended to become independent. The claims previously depended from claim 1 and the amendment merely adds the features of claim 1 to the formerly dependent claims. Support for the recitation of "wherein the methylcellulose does not overall cover over the medicament, and a part of the medicament exists on the surface of the particle" can be found in the Specification, page 21, lines 7-9.

No new matter has been added.

2. **Interview Summary**

The Examiner contacted Applicants' Representative to discuss the rejections of record in view of the Declaration of Dr. Shimono and the claim amendments made in the Amendment of November 5, 2010. The amendments to the claims presented in this paper were, in large part, suggested by the Examiner, as discussed below.

The Examiner called to discuss these issues to see if any or all of them could be resolved before she issues an Office Action. Applicants thank the Examiner for her pro-active approach and the effort to streamline prosecution in the present application. Applicants submit that the claim amendments and remarks below fully respond to the Examiner's concerns, and request that the present claims be allowed.

Declaration of Dr. Shimono filed on November 5, 2010

The Examiner commented that the method of making the particles presented in Dr. Shimono's Declaration is not the same as the process used in the Specification. Applicants wish to point out that Dr. Shimono testifies that in his opinion, despite the difference in the processes used, identical particles result. However, the Examiner was not convinced that the particles were the same.

In particular, the Examiner asserts that it is possible that the particles disclosed in the Specification are completely covered by the polymer (methylcellulose) because in the Shimono Declaration, the medicament is present in the solution sprayed on the particles during the granulation process, but not in the solution that is sprayed on the particles during the granulation process described in the Declaration.

The process of the Specification recites: "mixing the ingredients and then granulating the mixture with water or water-containing solvent; or a method for dissolving a part of methylcellulose in water, adding the solution to the mixture and then granulating it."

(Specification, page 19, lines 14- 18).

In Example 1, the particles are prepared by:

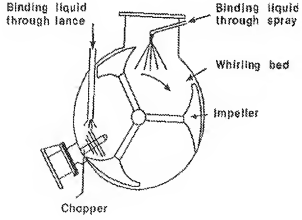
> all the ingredients comprised as a component of the medicament-containing particle are mixed and granulated in an agitating granulator (Powrex Corp., FM-VG-05) while spraying 130 g of purified water, and then dried in a tray type dryer. The resulting granules are sifted by means of a 32 mesh sieve (opening, 500 μm) to give medicament-containing particles whose average particle size is about 250 μm.

In the Declaration filed on November 5, 2010 the particles were prepared by the method described by Dr. Shimono:

> mannitol and methylcellulose were added to a fluid bed granulator (Powrex Corp., GPCG-120) and mixed and then a suspension of 4% HPC-L water-solution and mosapride citrate dehydrate (as a medicament) was spray-added to the fluid bed granulator in which the content was mixed and granulated. Then, the resulting granules were dried in the bed. (Declaration, filed November 5, 2010, page 2).

An example of the granulation process of the Specification is shown in the following figure:

a.



Here, the dry particles are formed by being subjected to a granulation liquid and granules, which are agglomerations of particles that stick together because they are dampened by the granulation

liquid. The particles and sprayed granulation fluid are mixed with an impeller to obtain the presently claimed particles.

An example of the process of the granulation process of the Shimono Declaration is shown in the following figure:

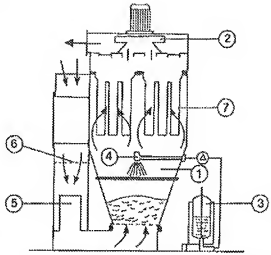


FIG. 9. Fluidized-bed granulator; (1) material container, (2) ventilator, (3) binder solution, (4) nozzle, (5) heating elements, (6) inlet air filter, (7) outlet air filter.

Here, the dry particles are placed under conditions which cause the dry particle bed to act like a fluid. This fluidized bed is subjected to a granulation liquid, and the particles and liquid are mixed with an air stream to form the granules of the present invention.

A further description of the machinery and both processes can be found in the attachment, Granulations, page 136-139.

Applicants' Representative submits that it is entirely reasonable, and more likely than not, that a similar distribution of medicament in the granulated particle will result whether the medicament is provided as a particle in the dry particle stream and sprayed with water compared to if the medicament is provided as a particle in suspension in the granulation liquid.

Nevertheless, the conclusion of the discussion on this point was that the Examiner alleges that the record lacks proof that the particles having the structure shown in the Shimono Declaration of November 5, 2011 have the taste characteristics shown in the Specification.

To address the Examiner's concern, Applicants herein present an additional Declaration of Dr. Shimono. This Declaration takes the uncoated particles made and analyzed in the Declaration of November 5, 2010, and uses them in a Taste Test as described in the Specification Tables 13-15.

As is shown in this additional Declaration, the "masking effect was clearly exhibited and the unpleasant taste was not felt at all" (Shimono Declaration, signed August 30, 2011, page 2).

Applicants submit that they have demonstrated that the claimed particles and the particles of the Declaration of Dr. Shimono from November 5, 2010 generate the same taste masking effect.

Claim Language

Next the Examiner discussed the particular language of the claims. First the Examiner addressed the amendment of claim 1. In her view, the Specification does not adequately support the recitation that the particle "lacks a coating." Applicants respectfully disagree.

Support for the language "lacks a coating" can be explicitly found in the Specification on page 21, lines 7-11. Implicit support for the lack of a coating can be found in the Specification in Example 1, page 29, lines 10 to page 30, line 4. Further support for the inherency of the lack of coating in view of the method of preparation of the particle can be found in the Declaration of Dr. Shimono, filed on November 5, 2010, page 2 point 6 and the attached photographs. In particular, Dr. Shimono comments that "the surfaces of the particles are scabrous. This type of structure indicates that the particles are not coated" (Shimono Declaration filed November 5, 2010, page 4).

Considering the process suggested by the Examiner as forming a coating, it would appear that all

three components of the particles are on the surface of the particle. If, as the Examiner suggests, methylcellulose from the bulk of the particle would make a coating over the particle when sprayed with water, then it stands to reason that the methylcellulose would cover the mannitol in the bulk of the particle as well. However, this is clearly not the case as shown by Figure 2 of the Declaration filed on November 5, 2011, where a particle is sprayed with both water and mosapride, yet mannitol is shown on the surface of the particle. Thus, Applicants submit that the Shimono Declaration of November 5, 2011 very clearly suggests that the particles made by the process of the Specification are also not completely coated by polymer. For this additional reason, Applicants submit that it is clear that the particles of the invention are not completely coated by polymer, and that the medicament is present on the surface of the particles.

Compilation Data from Specification

The Examiner next explained her view that the data presented in the compilation of data attached as a table to the last-filed Amendment do not quite establish criticality of the claimed ranges of the excipients to the taste-masking result. In particular, she is concerned that the data from Examples 4 and 16, which appear to be for embodiments outside the scope of the claims (the ratio of methylcellulose to medicament is only 0.5) give what seem to be the same taste test result (a circle) as Example 9, which is within the scope of the invention, albeit at the other end of the range for the ratio of methylcellulose to medicament.

First, Applicants submit that claim 1 has been amended to recite a ratio of methylcellulose to medicament of about 0.8 to about 5. Such a ratio thereby excludes Example 9 from the present claims. Applicants submit that all three of Examples 4, 9, and 16 represent embodiments near the "tails" of a bell-shaped curve, and so are at the edge of the invention. However, the Examiner indicated that she would like to see the claims narrowed to recite a range that more clearly demonstrates the unexpected results of the invention; i.e. that provides the "double circle" results.

In her opinion this would make the evidence of unexpected results more persuasive to her

supervisor.

Applicants disagree with the Examiner's assessment of the prior art, but note that the range of claim 4 has been incorporated into base claim 1 solely to further prosecution and without prejudice or disclaimer. That is, Examples 4, 9, and 16 are now all excluded from the claimed particles. Accordingly, Applicants submit that the claims are commensurate in scope with the data of the unexpected taste masking effect shown by the invention. Applicants request that the unexpected results of the claimed particles be recognized.

Claims 11 and 13-18

The Examiner suggested that claims 11 and 13-18 should be amended to recite a "... solid pharmaceutical preparation...", and claim 11 should be ended at "... acceptable ingredients." Applicants have amended the claims and submit that this should not be the basis for a future rejection.

Claim 19

The Examiner indicated that in her view, claim 19 is confusing, and also appears to expand the scope of claim 1 from which it depends. For example, claim 1 recites that the composition "consists essentially of" the listed ingredients, but claim 19 indicates that the composition "comprises" the listed ingredients. Applicants have cancelled claim 19 without prejudice or disclaimer, and submit that this should not be the basis for a future rejection.

Claim 20

Also, the Examiner suggested that claim 20 be rewritten to clarify that the solvent is only water, that is, that there is no polymer in the solvent. Applicants have amended claim 20 without prejudice or disclaimer and request that claim 20 not be the basis of a future rejection.

Claims 25-27

The Examiner suggested that claims 25-27 be rewritten into independent form, as she believes

that these claims expand the scope of claim 1 from which they depend. Applicants disagree, but have amended the claims to be independent without prejudice or disclaimer. Applicants request that these claims not be the basis of a future rejection.

Applicants submit that the present application claims subject matter free of the prior art. The favorable actions of withdrawal of the standing rejections and allowance of the pending claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: September 7, 2011

Respectfully submitted,

By: _____

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Attachments: 2nd Declaration of Dr. Shimono, dated August 30, 2011
Exhibit 1 - Excerpt from "Granulations", pages 136-139